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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,617	12/14/2001	Mark A. Heldreth	1671-0171	7934

7590

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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,617

Applicant(s)

HELDRETH ET AL.

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 14-16, 18-30, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 4, 8, 13, 10, 14, 17, 19 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/14/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it is too lengthy.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

See MPEP § 608.01(b). Appropriate correction is required.

Claim Objections

Claims 8, 10, 14 and 19 are objected to because of the following informalities. "trial insert" should be used instead of "insert trial" to be consistent with the disclosure. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al. (US 5,609,642).

Johnson et al. disclose a trial prosthesis assembly having a tray 11 with an opening that is configured to be supported on a proximal end of a resected tibia; a plastic insert or "evaluation member" 13 having a lower portion configured to be received in the opening of tray 11 such that

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rotational movement of evaluation member 13 relative to tray 11 is inhibited wherein tray 11 has an upper portion (28, 29) configured to support a trial prosthesis or "insert" 45 thereon (Figures 1-3, 5, 9 and 13; col. 5, lines 49-53; col. 6, lines 6-19; and col. 7, lines 28-38).

Claims 8-9, 11-12, 14, 21, 25-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Collazo et al. (US 5,872,925).

Collazo et al. disclose an apparatus or assembly with a tibial baseplate or trial tray 15 temporarily secured to a resected tibia with bone nails or "spikes" or "fixation pins" having a recessed cavity or opening 19, a spring clip activator or evaluation member or evaluation bullet 21, and a trial component or insert 7 with a recess 41 configured to receive evaluation member 21 wherein rotational movement of evaluation member 21 relative to tray 15 is inhibited by the side walls of opening 19. Collazo et al. also disclose that rotation or movement of trial insert 7 relative to the evaluation member 21 or tray 15 is prevented in a transverse plane while flexion and extension rotation or movement is enabled between both components (col. 3, lines 26-67; col. 4, lines 1-32; and Figures 1-4).

The method steps of claims 8-9, 11-12 and 14 are inherently performed during normal use of the Collazo et al. device for the purpose of attaining proper rotational alignment of a knee prosthesis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 15-16, 18, 20, 22, 23, 24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collazo et al. in view of McCue et al. (US 5,733,290).

Collazo et al. disclose an apparatus or assembly with a tibial baseplate or trial tray 15 temporarily secured to a resected tibia with bone nails or "spikes" or "fixation pins" having a

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recessed cavity or opening 19, a spring clip activator or evaluation bullet 21 adapted to receive a trial component or insert 7; wherein opening 19 has a recessed ledge to prevent evaluation bullet 21 from passing through opening 19. Collazo et al. also disclose that rotation or movement of trial insert 7 relative to the evaluation bullet 21 or tray 15 is prevented in a transverse plane while flexion and extension rotation or movement is enabled between both components (col. 3, lines 26-67; col. 4, lines 1-32; and Figures 1-4).

Although Collazo et al. disclose placement of tray 15 on a resected tibia using known techniques, Collazo et al. do not specifically disclose an alignment handle removably coupled to tray 15.

McCue et al. teach an alignment handle 10 removably coupled to trial tray 20 for aligning the tibial tray (Figure 1, col. 1, lines 5-7 and lines 39-54 and col. 2, lines 11-13 and lines 24-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an alignment handle 10, as taught by McCue et al., in the assembly of Collazo et al., for aligning trial tray 15 during knee replacement.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collazo et al., as applied to claim 8, in view Lackey et al. (US 5,702,464).

Collazo et al. do not disclose a plurality of trial inserts.

Lackey et al. teach a trial prosthesis with modular trial inserts that offer a series of articular topographies to provide a range of inserts with different articular geometries (col. 1, lines 8-13, col. 4, lines 12-19 and lines 27-34 and col. 5, lines 40-58).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of inserts, as taught by Lackey et al., in the apparatus of Collazo et al. for the purpose of providing a range of inserts with different articular geometries.

The method steps of claim 10 are performed during normal use of the apparatus of the combination of Collazo et al. and Lackey et al. for the purpose of knee replacement.

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Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collazo et al. in view of McCue et al., as applied to claim 15, further in view of Lackey et al.

Collazo et al. do not disclose a plurality of trial inserts.

Lackey et al. teach a trial prosthesis with modular trial inserts that offer a series of articular topographies to provide a range of inserts with different articular geometries (col. 1, lines 8-13, col. 4, lines 12-19 and lines 27-34 and col. 5, lines 40-58).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plurality of inserts, as taught by Lackey et al., in the apparatus of the combination of Collazo et al. and McCue et al., for the purpose of providing a range of inserts with different articular geometries.

Allowable Subject Matter

Claims 4, 13, 17 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

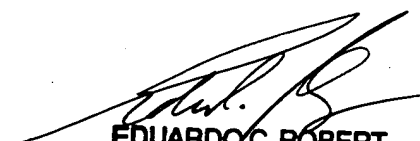
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anu Ramana*
September 27, 2003


EDUARDO C. ROBERT
PRIMARY EXAMINER